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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,023	10/08/2004	Lars I. E. Oddsson	BU-082XX	8760
207	7590	04/06/2006	EXAMINER	
WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP			SMITH, FANGEMONIQUE A	
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3736

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,023	<b>Applicant(s)</b> ODDSSON ET AL.	
	<b>Examiner</b> Fangemonique Smith	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/8/04</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1 and 37 are objected to because of the following informalities:
  - a. At line 15 of claim 1, it is suggested to modify the limitation “the magnitude” to read -- the detected magnitude -- to maintain consistent claim language.
  - b. At line 7 of claim 37, it is suggested to modify the limitation “said ankle signal” to read -- said ankle angle signal-- to maintain consistent claim language.Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 65 recites the limitation "angles between said at least one foot and said ipsilateral lower leg of said user" in lines 2 and 3. Claim 39, a claim from which claim 65 depends, recites an angle between at least one foot and an ipsilateral lower leg of a user. It is unclear whether the control signals are indicative of an angle or if the control signals represent a plurality of angles, rendering the claim indefinite.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-10, 14-20 and 23-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Crabb et al. (U.S. Patent Number 6,174,294).

In regard to claims 1-10, Crabb et al. disclose a limb load monitor, which provides feedback to a patient or user when a preselected force load is met or exceeded on the foot of the user. The monitor includes a plurality of sensors (14, 15) configured for placement as a two-dimensional array under at least one foot of a user. Each sensor transduces a detected magnitude of forces applied, and the plurality of sensors generate balance information signals representing the detected magnitude of forces applied (col. 3, lines 1-33). Sensors (14, 15) are sensitive to various forces applied to the foot of the user, including forces oriented parallel or perpendicular to the plurality of sensors to gather information needed for determining when the preset load has been exceeded (col. 2, lines 38-67; col. 3, lines 1-33). The Crabb et al. device further includes a signal processing subsystem, which receives balance information from the plurality of sensors and converts the balance information signals into stimulation control signals. The stimulation control signals are capable of processing signals to determine the magnitude of the pressure under the foot of the user, as well as the radial and angular position of the center of pressure under the foot. Stimulators are included in the Crabb et al. device providing feedback to stimulate the user in response to the stimulation control signals. The device disclosed by Crabb

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et al. is capable of feedback stimulation a manner indicative of the magnitude of the pressure under the foot and the radial and angular positioning of the center of pressure under the foot (col. 3, lines 1-33; col. 6, lines 55-67; col. 7, lines 1-18). The plurality of sensors can be attached to the shoe of a user. The sensors are also capable of being mounted in a stocking.

In regard to claims 14-20 and 23-34, Crabb et al. the signal processing subsystem is further operable to convert the collected balance information signals received from the plurality of sensors (14, 15) into data indicative of forces applied to a sole the foot and transmits the information to the stimulation control signals for feedback purposes. The Crabb et al. system is capable of determining a magnitude of a resultant reaction force applied to a sole of at least one foot of the user. The control box within the Crabb et al. system incorporates the stimulator signaling means of the device providing a visual, audio, vibratory or other type of feedback to the user upon placing the stimulator signaling means proximate with at least one sensory neuron of said user. The control box (20) is securable to a leg of said user in a plane substantially parallel to a plane of an ipsilateral foot sole or can be incorporated into a stocking (col. 2, lines 60-67; col. 3, lines 1-9). The control box is also capable of being secured on the head of the user.

In regard to claims 35 and 36, the stimulators of the Crabb et al. device are capable of stimulating a sole of at least one foot of the user. The stimulators of the Crabb et al. system are responsive to received stimulation control signals and the stimulus amplitudes, frequencies, and locations are indicative of at least one parameter describing forces applied to a sole of said at least one foot (col. 2, lines 60-67; col. 3, lines 1-33).

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In regard to claims 39-48 and 52-66, the Crabb et al. system comprises at least one sensor (14, 15) capable of determining an angle between at least one foot and an ipsilateral lower leg of a user and transmitting balance information representing the determined angle for analysis (col. 2, lines 60-67; col. 3, lines 1-33; col. 6, lines 55-67; col. 7, lines 1-18). The Crabb et al. device further includes a signal processing subsystem for receiving the balance information signal converting the balance information into stimulation control signals. The stimulation control signals are interpreted by the system and upon meeting predetermined threshold conditions, a plurality of stimulators placed on the user are activated to provide feedback (col. 2, lines 60-67; col. 3, lines 1-9). Crabb et al. disclose a control box (20) with stimulators being responsive to stimulation control signals to stimulate the user in a manner indicative of said angle between said at least one foot and said ipsilateral lower leg of said user. The system is capable of determining angles between the foot of the user and the lower leg. Additionally, the control box (20) disclosed by Crabb et al. is insertable into a shoe or stocking of the user. As described above, the signal processing subsystem of the Crabb et al. apparatus is capable of converting the balance information signal into an estimate of a magnitude of an angle between the foot and ipsilateral lower leg of the user. The control box within the Crabb et al. system incorporates the stimulator signaling means of the device providing a visual, audio, vibratory or other type of feedback to the user upon placing the stimulator signaling means proximate with at least one sensory neuron of said user. The control box (20) is securable to a leg of said user in a plane substantially parallel to a plane of an ipsilateral foot sole or can be incorporated into a stocking (col. 2, lines 60-67; col. 3, lines 1-9). The control box is also capable of being secured on the head, arm or trunk of the user. Furthermore, Crabb et al. disclose a system capable of determining an angle

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between one lower leg and the ipsilateral upper leg and transmitting a knee angle signal to determine stimulation control signals, at least in part, responsive to the knee angle signal.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 11-13, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crabb et al. (U.S. Patent Number 6,174,294) in view of Andrews (U.S. Patent Application Publication Number 2002/0055779).

In regard to claims 11-13, 21, 22 and 49-51, Crabb et al. disclose the features of the Applicant's invention as described above. Crabb et al. do not disclose a device implantable within the body of the user. Andrews discloses a neural prosthesis with a sensor having output representative of human body activity. The device disclosed by Andrews performs a body movement analysis according to the data provided by the implantable sensor. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a limb load monitor, similar to that disclosed by Crabb et al., to include an implantable sensor, similar to that disclosed by Andrews, to provide a more discrete analysis system while maintaining the functionality of the device.

9. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crabb et al. (U.S. Patent Number 6,174,294) in view of Andrews (U.S. Patent Number 4,745,930).

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In regard to claims 37 and 38, Crabb et al. disclose the features of the Applicant's invention as described above. Crabb et al. do not disclose the use of a goniometer to determine any angle information upon analysis of the data collected. Confer discloses a force sensing insole adapted to be used in association with an electro-goniometer for analyzing gait of a patient. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a limb load monitor, similar to that disclosed by Crabb et al., to include an electro-goniometer system, similar to that disclosed by Crabb et al., to provide additional motion information for determining forces exerted of the foot of the user without altering the natural motion of the foot.

10. Claims 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crabb et al. (U.S. Patent Number 6,174,294).

In regard to claims 68-70, Crabb et al. disclose the features of the Applicant's invention as described above. Crabb et al. do not disclose. Brown et al. discloses a foot analyzer which performs calculations on collected data to diagnose and treat various medical problems. The calculations performed by the foot analyzer disclosed by Brown et al. include calculating a center of pressure for performing sway analysis. The Brown et al. device also used to determine signal information including radial displacement as measures of time and frequency (col. 3, lines 16-67; col. 3, lines 1-59). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a limb load monitor, similar to that disclosed by Crabb et al., to include calculations which include determining a time relationship with collected data information, similar to that disclosed by Brown et al., to provide a thorough



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analysis of the motion of a foot under investigation while gathering information that could be used for medical diagnoses (col. 1, lines 50-67; col. 2, lines 1-10).


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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